
Clinical Development of an osteoinductive therapy to prevent osteoporosis-related fractures

Grant Award Details

Clinical Development of an osteoinductive therapy to prevent osteoporosis-related fractures

Grant Type: Disease Team Therapy Planning I

Grant Number: DR2-05368

Investigator:

Name:	John Hood
Institution:	Samumed, LLC
Type:	PI

Disease Focus: Bone or Cartilage Disease

Award Value: \$99,110

Status: Closed

Progress Reports

Reporting Period: Year 1

View Report

Grant Application Details

Application Title: Clinical Development of an osteoinductive therapy to prevent osteoporosis-related fractures

Public Abstract:

There are over 1.5 million osteoporotic fractures annually in the USA alone, at a cost of approximately \$15 billion each year. The majority of these fractures occur in the spine, followed by the hip and wrist. Incidence varies according to age; vertebral fracture rates increase rapidly by the sixth decade of life, whereas the risk of hip fracture rises markedly by the eighth decade and beyond.

Current treatment is focused on prevention using osteoclast inhibitors, hormone therapy, diet and exercise. When a fracture occurs current therapies involve injection of cement into the vertebral body and/or open surgery with implants. Unfortunately, these procedures do not regenerate bone tissue, often fail and incur risks of leakage and emboli. The clinical and economic impact associated with these fractures is substantial. Following a fragility fracture, significant pain, disability, and deformity can ensue. If fracture union is not achieved, the patient may suffer long-term disability. This is exacerbated because there is a five-fold increase in the risk for sustaining a subsequent vertebral fracture and the odds that a neighboring vertebrae will fail within one year is >20%. We propose to add a noninvasive anabolic option to the treatment and prevention of osteoporotic fractures. This therapy utilizes a novel small molecule Wnt pathway activator that drives the endogenous stem cells in the bone compartment to differentiate into bone forming osteoblasts thereby increasing bone mass and reducing the risk of fracture. This therapy will be administered 1-2X/year by injection, eliminating the concerns over patient compliance and revolutionizing the treatment of vertebral and hip fractures in patients suffering from osteoporosis.

Statement of Benefit to California:

There are over 25 million osteoporosis patients in the US alone, leading to 1.5 million osteoporotic fractures annually at a cost of approximately \$17 billion per year. The lifetime incidence of fragility fractures secondary to osteoporosis in females over fifty years of age is approximately 1 in 2, and in males over the age of fifty, is 1 in 4. Osteoporosis-related vertebral compression fractures are the most common fragility fractures in the United States, accounting for more than 79% of the total. Approximately 70,000 OVCFs result in hospitalization each year with an average hospital stay per patient of 8 days. Current treatment is focused on prevention using osteoclast inhibitors, hormone therapy, diet and exercise. When a fracture occurs, current therapies involve injection of cement into the vertebral body and/or open surgery with implants. Unfortunately, these procedures do not regenerate bone tissue, often fail, incur risks of leakage and emboli, and suffer significant side effects. The clinical and economic impact associated with these fractures is substantial. Following a fragility fracture, significant pain, disability, and deformity can ensue. If fracture union is not achieved, the patient may suffer long-term disability. This is exacerbated because there is a five-fold increase in the risk for sustaining a subsequent vertebral fracture after the first fracture, and the odds that an adjacent vertebrae will fail within one year is >20%. We propose to add a noninvasive anabolic option to the treatment and prevention of osteoporotic fractures, with minimal to no side effects or systemic safety concerns. This therapy utilizes a novel small molecule Wnt pathway activator that drives the endogenous stem cells in the bone compartment to differentiate into bone forming cells, thereby increasing bone mass and reducing the risk of fracture. This therapy will be administered 1-4 times per year by injection, eliminating the concerns over patient compliance and revolutionizing the treatment of vertebral and hip fractures in patients suffering from osteoporosis. This will benefit the citizens of California by reducing hospitalization periods, operative costs and loss of workdays, and by improving quality of life for Californians with osteoporosis that are at risk for OVCFs.

Source URL: <https://www.cirm.ca.gov/our-progress/awards/clinical-development-osteoinductive-therapy-prevent-osteoporosis-related>